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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/896,053	07/17/1997	STEFAN JANSSENS	0609.4280001	2698

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EXAMINER
WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
1632	31

DATE MAILED: 11/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/896,053	Applicant(s) Janssens
	Examiner Anne Marie Wehbé	Art Unit 1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 6/19/02 and 7/22/02 .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 22-25, 28-33, 35, 37, and 40-42 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) 22-25, 28-33, 35, and 40-42 is/are allowed.

6) ☒ Claim(s) 37 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's amendments received on 6/19/02 and 7/25/02 have been entered. Claims 38-39 and 43 have been canceled without prejudice. Claims 22-25, 28-33, 35, 37 and 40-42 are pending in the instant application. An action on the merits follows.

The text of those sections of Title 35, US code, not included in this action can be found in the previous office actions.

The objection to the oath or declaration is withdrawn in view of applicant's submission of the substitute declaration, paper no. 29.

Claim Rejections - 35 USC § 112

The rejection of claims 40-41 under 35 U.S.C. 112, first paragraph, for scope of enablement is withdrawn in view of applicant's amendment of the claims.

Claim Rejections - 35 USC § 102

The rejection of claims 37-39 and 43 under 35 U.S.C. 102(e) as being anticipated by

U.S. Patent No. 5,880,102 (3/9/99), hereafter referred to as George et al. is withdrawn in view of applicant's amendment or cancellation of the claims. However, please note that the amendment to pending claim 37 has necessitated new grounds of rejection of claim 37 under 35 U.S.C. 103(a) below.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 37 is newly rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,880,102 (3/9/99), hereafter referred to as George et al., in view of U.S. Patent No.

5,976,873 (11/2/99), hereafter referred to as Bohinski et al. The applicant's amended claim recites a pharmaceutical composition suitable for aerosol delivery comprising an adenoviral vector encoding a nitric oxide synthase gene operably linked to a pulmonary tissue specific expression control element.

George et al. teaches recombinant adenoviral vectors encoding an NOS isoform operatively linked to a promoter (George et al., column 77, claims 13 and 25, and column 78, claims 26-28). George et al. further teaches that the NOS isoform is endothelial NOS (George et al., column 5, lines 32-44). George et al. also teaches the use of said recombinant adenoviruses encoding NOS for *in vivo* administration in a mammal for the treatment of diseases such as vein graft failure and restenosis (George et al., columns 5-6). In addition, George et al. teaches the administration of an adenoviral vector encoding NOS in saline, a pharmaceutically acceptable carrier which is further suitable for aerosol delivery (George et al., column 6). Please note that although George et al. does in fact teach the intended use of the disclosed adenoviral vectors for pharmaceutical use *in vivo*, the intended use of a product for a particular purpose is not afforded patentable weight in a product claim where the body of the claim does not depend on the preamble for completeness but, instead, the structural limitations are able to stand alone. The MPEP states that,".. in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art." In re Casey, 152 USPQ 235 (CCPA 1967); In re Otto , 136 USPQ 458, 459 (CCPA 1963)(MPEP 2111.02).

While George et al. does not specifically teach a pulmonary tissue specific expression control element, George et al. does teach the administration of adenoviral-NOS to lung tissue and further provides motivation for using tissue specific promoters by stating, "[t]issue specific expression of the gene can be facilitated using tissue specific promoters" (George et al., column 4, lines 58-63, column 5, lines 49-50 and 62-66). Bohinski et al. supplements George et al. by teaching lung specific expression control elements that can be used in adenoviral vectors to direct expression of a therapeutic gene of interest in lung tissue (Bohinski et al., column 11, lines 47-67, and column 12, lines 1-16). Thus, in view of the motivation provided by George et al. that use of tissue specific expression control elements facilitates tissue specific gene expression and the teachings of George et al. for the administration of Ad-NOS to lung tissue, it would have been *prima facie* obvious to the skilled artisan to use the lung tissue specific expression control elements taught by Bohinski et al. in the adenoviral vectors encoding NOS taught by George et al. in order to specifically target expression of NOS to lung tissue. Furthermore, based on the high level of skill in molecular biology at the time of filing, the skilled artisan would have had a reasonable expectation of success in modifying the adenoviral vector encoding NOS taught by George et al. to include a lung specific expression control element as taught by Bohinski et al.

The objection to claims 25 and 33 under 37 CFR 1.75(c), as being of improper dependent form is withdrawn in view of applicant's arguments.

Claims 22-24, 28-32, 35, and 42 are considered allowable at this time.

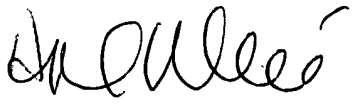
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Thurs and every other Friday from 9:30-7:00. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The

technology center fax number is (703) 308-4242, the examiner's direct fax number is (703) 746-7024.

Dr. A.M.S. Wehbé



ANNE M. WEHBE' PH.D
PRIMARY EXAMINER